



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: BALDWIN *et al.*

Serial No.: 09/391,783

Filed: September 8, 1999

Atty Dkt: 1073.008H

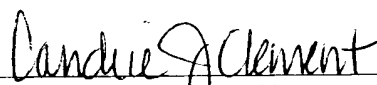
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RESPONSE TO REQUIREMENT for ELECTION of SPECIES UNDER 37 CFR §1.121

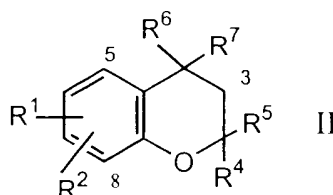
Dear Sir:

This is a reply to the Office communication mailed June 3, 2002 (paper number 14), which set a one month period for response. In light of the accompanying fee and request for an extension of time, a reply to the Action is due December 3, 2002, and this response is timely filed.

In light of a previous requirement for restriction and a subsequent amendment to add claims 39-49, claims 4-7 and 38-49 are pending in the application. The present Office Action requires Applicants to elect a single disclosed species for prosecution on the merits, to which the claims shall be restricted if no generic claim is found allowable. More specifically, the Action requires Applicants to "elect, **for purposes of a search**, a single, fully-defined compound. That is, all atoms and bonds of each and every variable group should be defined. . . . The instant species election requires that one - and only one- compound be elected; the elected species should contain no variable groups."

With regard to an election of species, Applicants elect the species defined as:

A compound of the formula:



wherein:

R^1 is $-OCH_2CO_2H$;

R^2 is $-H$;

R^4 and R^5 taken together are $-(CH_2)_2-S(O)_{0-2}-(CH_2)_2-$;

one of R^6 and R^7 is $-H$ and the other is $-H$ or $-N(CH_2)_{1-6}R^{14}R^{15}$;

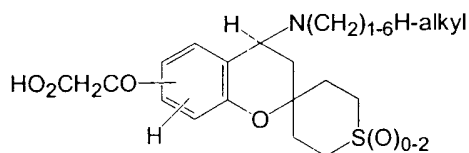
R^{14} is $-H$; and

R^{15} is alkyl,

or a pharmaceutically acceptable salt thereof.

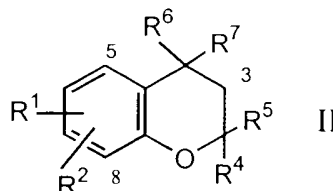
As required, each of the variables in generic Formula II, *i.e.*, R^1 through R^7 , has been defined. With respect to the definition of R^6 and R^7 , the variables R^{14} and R^{15} , have also been defined.

The elected species is represented by the structure:



The elected variable definitions are underlined and bolded in the following copy of generic claim 4.

4. A compound of the formula:



wherein:

R¹ is OH, O(CH₂)₁₋₂OH, **OCH₂CO₂H**, CO₂H, O-Z-C(O)NH(CH₂)₁₋₆R¹⁷ or OCH₂-4-Phe-C(O)NH(CH₂)₁₋₆R¹⁷;

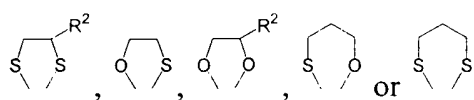
R² is **H** or lower alkyl;


R³ is H, alkyl, aryl, or arylalkyl;

R⁴ and R⁵ are each independently H, lower alkyl, or substituted lower alkyl where the substituents are 1-3 alkoxy, aryl, substituted aryl, carboalkoxy, carboxamido or di-loweralkylamido; or

R⁴ and R⁵ taken together are -(CH₂)_n-, -(CH₂)₂-O-(CH₂)₂-, -CH₂-O-(CH₂)₃-,
-(CH₂)₂-NR⁸-CH₂)₂-, -CH₂-NR⁸-(CH₂)_m-, -(CH₂)₂CH(NHR⁸)(CH₂)₂-,
-CH₂CH(N-loweralkyl)(CH₂)₂CHCH₂-,
-(CH₂)₂-S(O)₀₋₂-(CH₂)₂-, or

one of R⁶ and R⁷ is H and the other is H, OH, or N(CH₂)₁₋₆R¹⁴R¹⁵; or

R⁶ and R⁷ taken together are , with the proviso that when

R¹ is -OH and R² is -H, R⁶ and R⁷ are not -H and -OH or when taken together are not ;

R⁸ is H, COOR⁹, CONHR¹⁰, CSNHR¹¹, COR¹², SO₂R¹³, lower alkyl, aryl lower alkyl, heteroaryl, or heteroaryl lower alkyl, wherein aryl is optionally substituted with 1-3 substituents selected from lower alkyl, lower alkoxy, halo, CN, NH₂, COOH, CONH₂, carboalkoxy, and mono- or di-lower alkylamino and wherein heteroaryl is a mono- or bicyclic heteroaromatic ring system of 5 to 10 members including 1 to 3 heteroatoms selected from O, N, and S and 0-3 substituents selected from halo, amino, cyano, lower alkyl, carboalkoxy, CONH₂, and S-lower alkyl;

- R^9 is lower alkyl, aryl, aryl lower alkyl, heteroaryl, aryl substituted by 1-3 substituents selected from alkyl, alkenyl, alkoxy, methylene dioxy, and halo, or a 5- to 6-membered heterocyclic ring containing O or N as a heteroatom, wherein heteroaryl is a heteroaromatic ring of 5 to 6 members including 1 to 2 heteroatoms selected from O, N, and S and 0-2 substituents selected from lower alkyl, dialkylamino, lower alkoxy, and halo;
- R^{10} and R^{11} are each independently lower alkyl, aryl, aryl lower alkyl, or aryl substituted by 1-3 substituents selected from lower alkyl, halo, alkoxy and haloalkyl;
- R^{12} is lower alkyl, aryl, heteroaryl, aryl lower alkyl, heteroaryl lower alkyl, a 5- or 6-membered heterocyclic ring containing 1-2 heteroatoms selected from O, S, and N, a 5- or 6-membered heterocyclic ring containing 1-2 heteroatoms selected from O, S, and N-lower alkyl, or aryl substituted with 1-3 substituents selected from lower alkyl, alkoxy, halo, sulfamoyl, lower alkyl sulfamoyl, cyano, and phenyl;
- R^{13} is lower alkyl, aryl, or aryl substituted with 1-3 substituents selected from lower alkyl, alkoxy, halo, CN, and haloalkyl;
- R^{14} is H;** alkyl; alkyl substituted by 1-3 alkoxy, S-lower alkyl, sulfamoyl, halo, alkylsulphonamido, or arylsulphonamido; alkenyl; alkynyl; aryl; substituted aryl; heteroaryl; substituted heteroaryl; heterocycloalkyl; $-\text{CH}_2\text{NR}^{16}\text{C}(\text{O})\text{R}^{16}$; $-\text{C}(\text{O})\text{NR}^{16}\text{R}^{16}$; $-\text{CH}_2\text{OC}(\text{O})\text{R}^{16}$; or $-\text{CH}_2\text{SC}(\text{O})\text{R}^{16}$;
- R^{15} is H, alkyl,** $-\text{C}(\text{O})\text{X}$, $-\text{C}(\text{S})\text{X}$, or $-\text{C}(\text{NCN})\text{NR}^3\text{R}^3$;
- R^{16} is lower alkyl, substituted lower alkyl, aryl, or substituted aryl;
- R^{17} is H; alkyl; alkyl substituted by 1-3 alkoxy, S-lower alkyl, sulfamoyl, halo, alkylsulphonamido, or arylsulphonamido; alkenyl; alkynyl; aryl; substituted aryl; heteroaryl; substituted heteroaryl; heterocycloalkyl; $-\text{CH}_2\text{NR}^{16}\text{C}(\text{O})\text{R}^{16}$; $-\text{C}(\text{O})\text{NR}^{16}\text{R}^{16}$; $-\text{CH}_2\text{OC}(\text{O})\text{R}^{16}$; or $-\text{CH}_2\text{SC}(\text{O})\text{R}^{16}$;
- X is alkyl, aryl, arylalkyl, O-loweralkyl, or $-\text{NR}^3\text{R}^3$;
- Z is $-(\text{CH}_2)_{1-6}-$, optionally substituted with 1-3 lower alkyl; $-\text{CHR}^2-$; $-\text{Phe}-\text{CH}_2-$, where Phe is optionally mono-substituted with halogen, lower alkyl, or alkoxy; or heteroarylene- $(\text{CH}_2)-$;
- m is 2 or 3; and
- n is 4-9;
- or a pharmaceutically acceptable salt thereof.

With regard to the remaining pending claims, claims 38-39 and 41 read on the elected species.

Respectively submitted,

December 3, 2002



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